

WHAT IS CLAIMED IS:

1. A method for the prevention or treatment of diabetes comprising:
administering to a human subject in need of prevention or treatment, a pharmaceutical
composition comprising a Type 1 diabetes autoantigen or immunologically active fragment
or variant thereof and an oil-based carrier.

2. The method of claim 1, wherein the autoantigen is selected from the group
consisting of: preproinsulin, GAD 65, ICA512/IA-2, HSP60, carboxypeptidase H, peripherin,
and ganglioside.

3. The method of claim 1, where the autoantigen is preproinsulin or an
immunologically active fragment or variant thereof.

4. The method of claim 3, wherein the autoantigen is human insulin B-chain or
an immunologically active fragment or variant thereof.

5. The method of claim 4, wherein the insulin B-chain fragment comprises
amino acids 33-37 of SEQ ID NO:1.

6. The method of claim 1, wherein the autoantigen is GAD65 or an
immunologically active fragment or variant thereof.

7. The method of claim 1, wherein the pharmaceutical composition is a vaccine.

8. The method of claim 1, wherein the autoantigen is a synthetic peptide.

9. The method of claim 1, wherein the oil based carrier is IFA or Montanide ISA
or an equivalent composition.

10. A pharmaceutical composition comprising a type 1 diabetes autoantigen and
an oil-based adjuvant.

11. The pharmaceutical composition of claim 10, wherein the autoantigen is selected from the group consisting of: preproinsulin, GAD 65, ICA512/IA-2, HSP60, carboxypeptidase H, peripherin, and ganglioside.

5

12. The pharmaceutical composition of claim 10, wherein the autoantigen is preproinsulin or an immunologically active fragment thereof.

13. The pharmaceutical composition of claim 12, wherein the autoantigen is human insulin B-chain or an immunologically active fragment or variant thereof.

10

14. The pharmaceutical composition of 13, wherein the insulin B-chain fragment comprises amino acids 33-37 of SEQ ID NO:1.

15

15. The pharmaceutical composition of claim 10, wherein the autoantigen is GAD65 or an immunologically active fragment or variant thereof.

16. The pharmaceutical composition of claim 10, wherein the autoantigen is a synthetic peptide.

20

17. The pharmaceutical composition of claim 10, wherein the oil-based adjuvant is IFA or Montanide ISA or an equivalent composition.

18. The pharmaceutical composition of claim 13, wherein the human insulin B-chain is solubilized in urea.

25

19. A kit for preventing or treating type 1 diabetes comprising: a human type 1 diabetes autoantigen or immunologically active fragment or variant thereof, an oil-based carrier, and instructions indicating suitability for human use.

30

20. The kit of claim 19, wherein the autoantigen is selected from the group consisting of: preproinsulin, GAD 65, ICA512/IA-2, HSP60, carboxypeptidase H, peripherin, and ganglioside.

21. The kit of claim 19, wherein the autoantigen is a synthetic peptide.

22. The kit of claim 19, wherein the autoantigen is lyophilized.

23. The kit of claim 19, wherein the autoantigen is human insulin B-chain or an immunologically active fragment or variant thereof.

24. The kit of claim 19, wherein the oil-based carrier is IFA or Montanide ISA or an equivalent composition.

25. A method of enabling a health care provider to prevent or treat type 1 diabetes in a human subject, the method comprising:

providing a health care provider with a human diabetes type 1 autoantigen or immunologically active fragment or variant thereof;

optionally providing the health care provider with an oil-based carrier; and

providing the health care provider with instructions for use of the autoantigen to treat the subject.

26. The method of claim 25, wherein the autoantigen is selected from the group consisting of: preproinsulin, GAD 65, ICA512/IA-2, HSP60, carboxypeptidase H, peripherin, and ganglioside.

27. The method of claim 25, wherein the autoantigen is a synthetic peptide.

28. The method of claim 25, wherein the autoantigen is lyophilized.

29. The method of claim 25, wherein the autoantigen is human insulin B-chain or an immunologically active fragment or variant thereof.

30. The method of claim 25, wherein the oil-based carrier is IFA or Montanide
5 ISA or an equivalent composition.